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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| GAMBEL, PHILLIP | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/774,118 | LE ET AL. | |
| | Examiner | Art Unit | |
| | Phillip Gambel | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1-29 are pending.

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.
See United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

Applicant should update the status of USSN 09/756,301, now U.S. Patent No. 6,790,444.

3. The filing date of the instant claims is deemed as follows.

It appears that claims 1-9, 13-14, and 29 have a priority date at least of USSN 07/670,827, filed 3/18/91.

It appears that claims 15-23 and 27-28 have a priority date of at least USSN 07/853,606, filed 3/19/92.

However, other than the original claims,
the priority date and the antecedent support in the instant specification as filed for the recitation of "at least 1 µg/ml", "at least 15 ng/ml", and "at least about 100 ng/ml" is not readily apparent.
Therefore, claims 10-12 and 24-26 have a priority date of the instant application USSN 10/774,118, filed 2/6/2004.
If applicant desires priority for these "ng/ml limitiations" prior to 2/6/2004,
applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

Given the number of continuation-in-part applications, applicant is invited to clarify the support under 35 U.S.C. § 112, first paragraph, for the priority of the instant claims in the lineage of priority documents for establishing the record for clarity.

Therefore, this application repeats a substantial portion of prior USSN 09/756,301, filed 1/8/2001 and adds and claims additional disclosure not presented in the prior application, as indicated above. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Therefore, applicant should amend the first line of the specification to indicate the status of the instant application as a continuation-in-part.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

4. This application appears to be compliant with the Sequence Rules.

Applicant is invited to review the instant application to make sure that the appropriate SEQ ID NOS. are provided where required.

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

6. Claims 2, 6-9, 13, 16, 20-22, 27 and 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 7, 21 and 29 are indefinite in the recitation of "cA2" because its characteristics are not known. The use of "cA2" antibodies as the sole means of identifying the claimed antibodies renders the claim indefinite because "cA2" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct hybridomas / cell lines.

Applicant is invited to clarify the metes and bounds of the claimed cA2 antibody.

B) Claims 2 and 16 are indefinite in the recitation of "inhibits a pathological activity of TNF-α" because the recitation of the nature, parameters and endpoints are ill-defined and ambiguous, which renders the claims indefinite. This "limitation" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

C) Claims 6, 8, 9, 20 22 and 23are indefinite in the recitation of "high affinity", "affinity ... ", because these "limitations" are relative in nature, which renders the claims indefinite. These "limitations" are not defined by the claim and the specification does not provide a standard for ascertaining the critical parameters or requisite degree, and, in turn, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicant is invited to amend the claims to recite an assay by which the "affinity" is measured.

D) Claims 13 and 27 lack proper antecedent basis in that the dependent claims recite "a detectably labeled form", while the independent claims are limited to "an antibody" and not "a labeled antibody". Therefore, the dependent claims recite a structure not supported by the independent claims, limited to "antibodies" and not "labeled antibodies".

Applicant is invited to amend the claims to recite a preamble such as "a labeled antibody" and then define the antibody and the label to obviated this rejection.

E) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(l).

Correction of the following is required:

As indicated above with respect to priority and upon a review of the instant specification, it does not appear that the instant specification provides for antecedent basis for the recitation of "at least 1 μg/ml", "at least 15 ng/ml", and "at least about 100 ng/ml" is not readily apparent.

Alternatively, applicant is invited to identify the written support for instant claims in the specification as filed (and as well as any USSN document relied upon for priority).

9. Claims 1-29 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

A) Claims 1-29: The instant claims recite "at least a part of a non-human immunoglobulin variable region" and "at least a part of a variable region".

It has been well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. All of the heavy and light chain CDRs should be in their proper order and in the context of framework sequences which maintain their required conformation in order to provide a binding molecule having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites.

Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function. Single amino changes to either a CDR or even in certain circumstances to the framework can result in decrease affinity of antigen or even ablation of antibody binding and specificity.

While it is acknowledged that the recitation of the claims indicates that the "Variable region is capable of binding an epitope of TNFα", the claimed "chimeric antibodies" only require "a part of a variable region".

It is unlikely that any TNFα-specific antibody broadly encompassed by the claimed invention as defined by the claims will have the required binding function for TNFα and, in turn, have the required other properties and characterisitics (e.g. "affinity", "inhibits a pathologic activity of TNFα") encompassed by the claimed invention.

The specification provides insufficient direction and guidance regarding how to produce any "TNFα-specific antibody" broadly encompassed by the claimed invention.

Undue experimentation would be required to produce the invention commensurate with the scope of the claims from the instant disclosure alone. One of skill in the art would neither expect nor predict the appropriate functioning of the claimed TNFα – specific antibodies as broadly as is claimed. Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

Without sufficient guidance, the changes which can be made in the structure of the claimed TNFα-specific antibodies and still provide or maintain sufficient or the claimed activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Applicant is invited to amend the claims to recite or account for the structural elements that account for a chimeric antibody that can bind to TNFα as supported by the disclosure of the instant specification as filed in order to obviate this rejection.

B) Claims 7, 21 and 29: It is apparent that the cA2 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Affidavits and declarations, such as those under 37 C.F.R. § 1.131 and 37 C.F.R. § 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit, the applicant should make the remarks of record in the later application and include a copy of the original affidavit filed in the parent application.

Given the disclosure and the claims encompassing the instant cA2 antibody set forth in U.S. Patent No. 5,919,452; the conditions for the deposit of biological materials under 35 USC 112, first paragraph, with respect to cA2 appear to have been satisfied.

However, applicant is required to make the record clear exactly what is the scope of the instantly claimed A2 and cA2 antibodies and whether applicant has satisfied the deposit requirements under 35 USC 112, first paragraph, for the claimed A2 and cA2 antibodies.

If applicant is relying upon sequence information to satisfy the deposit of biological materials, i is noted that the sequence of an entire immunoglobulin satisfies the biological deposit of said immunoglobulin. Note that satisfaction for the biological deposit of the specific cA2 antibody requires the disclosure and recitation of its entire amino acid sequence and not based upon partial sequences

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. As addressed above and given the priority date attributed to claims 10-12 and 24-26, the following prior art rejection is set forth.

Claims 10-12 and 24-26 are rejected under 35 U.S.C § 102(b) as being anticipated Le et al. (WO 92/16553) (1449; #AN4) (see entire document).

Le et al. teach the generation of recombinant cA2-specific anti-TNF-α antibodies (e.g. see pages 9-11; page 13, paragraph 1 and Examples on pages 45- 74) of the instant invention (see entire document, including Description of the Prior art, Summary of the Invention, Detailed Description of the Preferred Embodiments and Claims). In addition, Le et al. teach the determination of those amino acid sequences of cA2-specific epitopes as well as means of testing functional attributes (See Examples XIII – XIV on pages 62 –70). Given the prior art teachings drawn to the same recombinant / chimeric cA2 antibodies, the prior art teaches antibodies that competitively inhibit the bindig of cA2 antibodies. Le et al. does teach that the recombinant antibodies can employ the constant region of any desired human immunoglobulin isotypes, including IgG1. In addition, given the therapeutic uses of said recombinant cA2-specific anti-TNF-α antibodies (see pages 35-38), the prior art cA2-specific anti-TNF-α antibodies could inhibit a pathological activity of human TNF-α.

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

13. Claims 1-6, 8-12 and 14 are rejected under 35 U.S.C § 102(a)(b) as being anticipated Jonker et al. (EP 0387095) (see entire document).

Jonker et al. teach the generation of anti-TNF-α antibodies, including the generation of recombinant chimeric antibodies (e.g. see page 3, paragraphs 4-5) for the treatment of immunoregulatory disorders (e.g. see pages 2-3, overlapping paragraph) see entire document, including Claims).

Given the prior art teachings drawn to the recombinant / chimeric anti-TNF-α antibodies that inhibit human immunoregulatory disorders, the prior art antibodies would have had the inherent properties encompassed by the claimed invention such as "inhibiting a pathological activity of human TNF-α" as well as the claimed affinities, including the high affinity.

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

The burden is on the applicant to establish a patentable distinction between the claimed and referenced recombinant / chimeric anti-TNF-α antibodies that inhibit human immunoregulatory disorders

Given the differences in priority dates of the instant claims, this rejection is made under both 35 USC 102(a) and (b).

14. Claims 1-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jonker et al. (EP 0387095) (1449; #AN4) AND/OR Moller et al. (Cytokine 2: 162-169, 1990) (1449; #AT4) in view of the known procedures to make and use recombinant chimeric antibodies at the invention was made, as taught by Zerler (EP 380,068 ) (1449; #AP) and Queen et al. (WO 89/09622).

Jonker et al. teach the generation of anti-TNF-α antibodies, including the generation of recombinant chimeric antibodies (e.g. see page 3, paragraphs 4-5) for the treatment of immunoregulatory disorders (e.g. see pages 2-3, overlapping paragraph) see entire document, including Claims).

Jonker et al. differs from the claimed antibodies by not describing the known use of human IgG1 in therapeutic chimeric antibodies at the time the invention was made.

Moller et al. teach anti- TNF-α antibodies, including their ability to neutralize the cytotoxicity of TNF-α in vitro and to block the lethal effects of TNF-α in vivo (e.g., see pages 164-165) as well as labeled antibodies (e.g., see page 167) (see entire document).

Moller et al. differs from the claimed antibodies by not describing the known generation of chimeric antibodies of antibodies of interest at the time the invention was made.

Zerler et al. teach the generation of chimeric antibodies, including the generation of chimeric antibodies, including the use of IgG1 in chimeric antibodies (e.g., see page 5, lines 53-55) to decrease immunogenicity of therapeutic antibodies as well as to provide a desired effector function (see Background of the Invention) (see entire document). In addition, Zerler et al. teach targeting TNF-α (e.g. see page 3, paragraph 6) as well as the construction of Chimeric Monoclonal Antibodies Against TNF (e.g. see pages 10-11).

Similarly, Queen et al. teach the generation of chimeric antibodies, including the use of different human constant regions, including IgG1, to provide for increase half-life as well as effector functions of interest (e.g., see page 6-7), as well as the use of labeled antibodies (e.g. page 16, paragraphs 2-3) and immunotoxins (e.g. see page 12, paragraph 5 – page 13) (e.g. see entire document, particularly the Detailed Description of the Invention).

Given the prior art teachings of the applicability of therapeutic chimeric antibodies as well as therapeutic TNF-specific antibodies to treat inflammatory diseases or disorders where the ordinary artisan desired to neutralize the inflammatory effects of TNF, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate chimeric antibodies and/or provide the IgG1 constant region in such chimeric antibodies of inhibitory anti-TNF antibodies such as that taught by Moller et al. and Jonker et al. to increase the half-life and to provide the desired effector functions of a desired human constant region such as IgG1 for their use as immunosuppressive reagents as taught by Moller et al., Jonker et al. and Zerler et al. or as diagnostics, as taught by Queen et al. Given the properties of the prior art anti-TNF antibodies, including their use as anti-inflammatory therapeutic agents, the claimed functional properties, including affinity would have expected or intrinsic properties of such antibodies based upon their known inhibitory properties as well as desired affinity to achieve therapeutic and diagnostic utilities. As taught by the prior art, labeled antibodies including labeled chimeric antibodies of interest were well known and practiced at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. It is noted that applicant has a number of copending applications in the instant family of applications with the same cA2 TNF-specific antibodies.

Again, given the history of a number of continuations-in-part, it is not readily apparent whether the claims were subject to restriction and whether the claims are subject to double patenting rejections.

Applicant is invited to clarify which applications should be subject to rejections under the judicially created doctrine of obviousness-type double patenting.

17. Claims 1-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over
claims 1-14 of U.S. Patent No. 6,284,471;
claims 1-9 of U..S. Patent No. 6,790,444; and
claims 1-9 of U..S. Patent No. 7,070,775.

Although the recitation of the instant and patented claims differ, all of the instant and patented claims are drawn to the same or nearly the same cA2-specific TNF-α-specific antibodies having the same or nearly the same functional properties of neutralizing TNF-α. The patented claims anticipate the instant claims.

18. Claims 1-29 are provisonally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over
claims of copending USSN 11/400,787 and
claims 1, 3-5, 8-12, 23 and 25 of copending USSN 11/143, 926.

The instant claims as well as the patented claims either anticipate or render obvious one another, given that both are drawn to the same or nearly the same TNFalpha - / ca2-specific antibodies. The copending claims anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 30, 2006